

receives its pricing information, BAYER agrees that, upon the receipt of a written request from the STATE, it will report the prices to a drug pricing reporting source other than, and in addition to, First DataBank, subject to reasonable provisions equivalent to those in place with First DataBank to ensure the confidentiality of that information.

- b) Average Sale Price Reporting Procedure: The price reported by BAYER with respect to each dosage form, strength and volume of the drug or biological product (without regard to any special packaging, labeling, or identifiers on the dosage form or product or package), shall be the average of all final sale prices charged by BAYER for the drug or biological product in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of "Best Price" for Medicaid Rebate Program purposes, pursuant to 42 USC § 1396r-8, and direct sales to hospitals. The prices identified in the calculation of the average sale price should be net of all the following: volume discounts; prompt pay discounts; cash discounts; chargebacks; short-dated product discounts; free goods; rebates\* and all other price concessions provided by BAYER to any relevant purchaser, as earlier defined in this paragraph, that result in a reduction of the ultimate cost to the purchaser. Notwithstanding the foregoing, the average sale price shall not include the value of bona fide charity care or grants. The average sale price reported shall be properly weighted to reflect

the volume of sales at each sale price, *i.e.*, for each NDC code, the price reported shall be an average per unit price determined by dividing the sum of all final prices charged by BAYER, net of all price reductions as defined above, for a drug or biological product in a quarter by the total number of units of that drug or biological product sold in that quarter. The methodology by which BAYER has calculated average sale prices in accordance with these standards shall be identified to the STATE as provided in Paragraph III.8(d).

- c) Limitations on Reporting of Average Wholesale Price: With respect to the Qui Tam Drugs, BAYER shall not report an AWP to First DataBank, or any other reporting service, to be used for purposes of setting Medicaid reimbursement prices for the Qui Tam Drugs, and BAYER shall expressly inform such reporting services to this effect. This restriction shall not limit BAYER's ability to report AWP information for the Qui Tam Drugs to price reporting services for uses unrelated to Medicaid, or its ability to report AWP information for any purposes for drugs or biological products other than the Qui Tam drugs.
- d) Certification Requirement: With each report of average sale price information BAYER sends to the STATE Medicaid Agency, BAYER shall also provide a detailed description of the methodology used to calculate the average sale price. A high managerial agent of BAYER

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\* The term "rebate" as used here is not understood to include any payments made by BAYER to the States pursuant to the Medicaid Rebate Program.

will certify that the average sale prices reported therein are the prices that have been reported to First DataBank, or any successor reporting agency, and that they have been calculated in accordance with the described methodology. Said certification shall be in the form annexed to this Agreement and shall include an acknowledgment that the average sale prices reported will be filed with and used in the administration of the STATE's Medicaid program. To the extent that BAYER's methodology involves accruing for the impact of future events, BAYER shall include a description of its accrual methodology in its certification, and shall on a quarterly basis evaluate such methodology in light of its actual experience and make any appropriate adjustments.

- e) It is understood that BAYER considers the average sale price information and the methodology by which it is calculated to be confidential commercial information and proprietary trade secrets that if disclosed would cause substantial injury to the competitive position of BAYER. It is further understood, however, that all information provided by BAYER to the STATE Medicaid Program pursuant to this Agreement shall be made available to the STATE's MFCU upon request.
- f) BAYER agrees to submit average sale price information in accordance with this paragraph for a period of five years from the Effective Date of this Agreement.

g) BAYER shall retain all workpapers and supporting documentation relating to the average sale prices of its drugs for six years after the date of each certification and will make such documentation available for inspection by the STATE's Medicaid Program and the STATE's MFCU.

9) BAYER waives and will not assert any defenses BAYER may have to any criminal prosecution or administrative action relating to the Covered Conduct, which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the United States Constitution or any corresponding section of the STATE's Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the United States Constitution or the corresponding section of the STATE's Constitution, this settlement bars a remedy sought in such criminal prosecution or in any administrative action that has not been released pursuant to this Agreement.

10) BAYER covenants to cooperate fully and truthfully with the STATE in any ongoing investigation or investigation commenced within five years of the Effective Date of this Agreement of individuals and entities not specifically released by this Agreement (including any parties with whom BAYER has or has had a business or professional relationship, including but not limited to vendors, contractors, partners, joint venturers, physicians, and referral sources) relating to the Covered Conduct. More specifically, upon reasonable request from the STATE:

(a) BAYER will make reasonable efforts to facilitate access to, and encourage the cooperation of, its current and former directors, officers, and

employees for interviews and testimony relating to the Covered Conduct, consistent with the rights and privileges of such individuals. To encourage the cooperation of such individuals, BAYER agrees to advise such individuals in writing that the STATE wishes to interview them or seek their testimony, and that the individuals' cooperation is in the best interest of BAYER. Cooperation provided pursuant to this subparagraph will include identification of witnesses who, to BAYER's knowledge, may have material information related to the STATE's inquiry. The testimony referred to in this paragraph includes, but is not limited to, testimony deemed necessary by the STATE or a court to identify or establish the source, original location, authenticity, or other evidentiary foundation for any documents and to authenticate such documents in any criminal, civil and administrative investigations and proceedings in which the STATE is involved.

- (b) BAYER will provide copies of non-privileged documents and records in its possession, custody or control relating to the Covered Conduct and relating to the subject of the STATE's inquiry. In connection with this, BAYER shall provide such technical assistance as is necessary to facilitate the STATE's access to any computerized information covered by this Paragraph.
- (c) Nothing in this agreement shall be construed as a waiver by BAYER of its attorney-client privilege or work product privilege. Notwithstanding that

fact, the existence of any such privilege does not affect BAYER'S obligation to comply with this Agreement.

- 11) This Agreement is intended to be for the benefit of the Parties only and, except as stated herein, the Parties do not by this instrument release any claims against any other person or entity, including any individual or entity that purchased drugs or biological products from BAYER.
- 12) The STATE acknowledges BAYER's cooperation in the STATE's investigation of drug pricing practices and agrees to communicate the nature and extent of this cooperation to other parties upon the request of BAYER. The making of this Agreement, and BAYER's provision of information pursuant to it, shall not be construed by the STATE as a basis for the exclusion of any of BAYER's products from the STATE's formulary.
- 13) Concurrent with the execution of this Agreement and payment of the Settlement Amount, the STATE agrees to dismiss with prejudice any lawsuit against BAYER, including any STATE qui tam "whistleblower" lawsuit currently pending against BAYER in the courts of the STATE, relating to the Covered Conduct.
- 14) Nothing in this Agreement shall be construed to abrogate or alter any existing obligation of BAYER pursuant to State law.
- 15) This Agreement, including all exhibits, constitutes the complete agreement between the Parties and may not be amended except by written consent of the Parties.
- 16) Each party to this Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

17) This agreement is governed by the laws of the State of Montana.

18) Unless otherwise stated in writing subsequent to the Effective Date of this Agreement, all notifications and communications made pursuant to this Agreement shall be submitted to the entities listed below:

**STATE :**

**[For the submission of average sale price data]**

**Pharmacy Director  
42 Olive Street  
Helena, Montana 59601**

**[For legal notices and all other purposes]**

**State of Montana  
Office of the Attorney General  
Medicaid Fraud Control Unit  
303 N. Roberts Street, Room 367  
Helena, Montana 59620**

**BAYER:**

**Assistant General Counsel  
Bayer Corporation Pharmaceutical Division  
400 Morgan Lane  
West Haven, CT 06516**

19) BAYER represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

20) The undersigned individuals signing this Agreement on behalf of BAYER represent and warrant that they are authorized by BAYER to execute this Agreement. The undersigned STATE signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

- 21) Each party agrees to perform any further acts and to execute and deliver any further documents reasonably necessary to carry out this Agreement. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement.
- 22) The parties have read the foregoing Agreement and accept and agree to the provisions contained therein and hereby have caused this Agreement to be signed as of the day and date adjacent to their signature.
- 23) The Effective Date of this Agreement shall be the date upon which all the parties below have executed this Agreement.

State of Montana  
Office of Attorney General  
Medicaid Fraud Control Unit

Bayer Corporation

By: Verlinda Seeling Date: 2/21/01

By: Paul R. Brey Date: 8/6/01

Title: Assistant Attorney General

Title: Vice President & Asst. General Counsel

✓ State of Montana Medicaid Program

Sidley & Austin, Counsel for BAYER

By: Janet C. Davis Date: 2/22/01

By: Paul E. Kalb Date: 8/1/01

Title: ADMINISTRATOR

Paul E. Kalb, Esq.  
I. Scott Bass, Esq.  
Robert Fabrikant, Esq.



**Exhibit "A"**  
**Participating States**

ALABAMA  
ALASKA  
ARKANSAS  
CALIFORNIA  
COLORADO  
CONNECTICUT  
DELAWARE  
FLORIDA  
GEORGIA  
HAWAII  
IOWA  
ILLINOIS  
INDIANA  
KANSAS  
KENTUCKY  
LOUISIANA  
MASSACHUSETTS  
MARYLAND  
MAINE  
MICHIGAN  
MINNESOTA  
MISSOURI  
MISSISSIPPI  
MONTANA  
NORTH CAROLINA  
NEW HAMPSHIRE  
NEW JERSEY  
NEW MEXICO  
NEVADA  
NEW YORK  
OHIO  
OKLAHOMA  
OREGON  
PENNSYLVANIA  
RHODE ISLAND  
SOUTH CAROLINA  
SOUTH DAKOTA  
TEXAS  
UTAH  
VIRGINIA  
VERMONT  
WASHINGTON  
WISCONSIN  
WEST VIRGINIA  
WYOMING

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**Exhibit "B"**  
**Threshold States**

ALABAMA  
ARKANSAS  
CALIFORNIA  
CONNECTICUT  
FLORIDA  
ILLINOIS  
LOUISIANA  
MASSACHUSETTS  
MARYLAND  
MICHIGAN  
MINNESOTA  
MISSOURI  
NORTH CAROLINA  
NEW JERSEY  
NEW YORK  
OHIO  
PENNSYLVANIA  
SOUTH CAROLINA  
TEXAS  
VIRGINIA  
WASHINGTON  
WISCONSIN

**Exhibit "C"**  
**Certification Form**

**CERTIFICATION**

The undersigned, a high managerial agent of Bayer Corporation, hereby certifies that the attached average sale price information has been communicated to First DataBank and that it has been calculated in accordance with the methodology described herein. I further acknowledge that the average sale prices so reported will be filed with and used in the administration of the State of Montana Medicaid program.

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Signature

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Title

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Date

**Exhibit 2**

## STATE SETTLEMENT AGREEMENT AND RELEASE

### **I. PARTIES**

This Settlement Agreement ("Agreement") is entered into by the state of Montana and Bayer Corporation ("Bayer"), an Indiana corporation with a principal place of business in Pittsburgh, Pennsylvania, hereinafter referred to as "the Parties."

### **II. PREAMBLE**

As a preamble to this State Agreement, the Parties agree as follows:

A. This Agreement addresses the claims against Bayer for the conduct described in filings in United States v. Bayer Corporation, Criminal Action No. [to be assigned](District of Massachusetts)(the "Criminal Action"), and in filings in United States ex rel. Couto v. Bayer Corporation, Civil Action No. 00-CV-10339 (District of Massachusetts)(the "Civil Action") for the conduct alleged in Preamble Paragraph F below.

B. On or before April 16, 2003, or some other date as may be determined by the Court, Bayer has agreed to or has entered a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to a one-count Information alleging a violation of Title 21, United States Code, Sections 331(p), 333(a)(2) and 360(j) by failing to list a drug product with the FDA between August and December 1995, namely, Cipro, that was private labeled by Bayer for Kaiser Permanente Medical Care Program ("Kaiser").

C. At all relevant times, Bayer marketed and sold pharmaceutical products nationwide, including among other drugs, two prescription drug products: (1) ciprofloxacin hydrochloride tablets, an antibiotic, marketed under the brand name Cipro®; and (2) nifedipine extended release tablets, an anti-hypertensive, marketed under the brand name Adalat CC® (collectively, "the drugs"). Bayer sold the drugs to various customers including, among others, health maintenance organizations ("HMOs"), hospitals, long term care providers, and chain pharmacies. Two HMOs that purchased the drugs from Bayer were Kaiser and PacifiCare

Health Systems ("PacifiCare"). PacifiCare purchased the drugs from Bayer through Prescription Solutions, a pharmacy benefit manager and wholly owned subsidiary of PacifiCare.

D. Effective August 1995, Bayer agreed to private label Cipro for Kaiser and to sell the private labeled Cipro to Kaiser at a discounted price. The term "private labeled" as used herein, means drug product that Bayer sold to a purchaser to which Bayer affixed a label that substituted the purchaser's national drug code ("NDC") for Bayer's NDC number. Effective April 1997, Bayer agreed to private label Adalat CC for Kaiser and to sell the private labeled Adalat CC to Kaiser at a discounted price. Effective October 1998, Bayer agreed to private label Adalat CC for PacifiCare and to sell the private labeled Adalat CC to PacifiCare at a discounted price.

E. At all material times, Bayer participated in the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, which is part of the federal Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v. As a participant in the Medicaid Rebate Program, Bayer entered into a rebate agreement with the Secretary of the Department of Health and Human Services, which agreement is administered by the Health Care Financing Administration ("HCFA"), currently known as the Center for Medicare and Medicaid Services ("CMS"), and Bayer's drug products were covered by state Medicaid plans that provided medical assistance for outpatient prescription drugs. 42 U.S.C. §§ 1396a(10)(A); 1396d(a)(12), and 1396r-8(a)(1). Under the Medicaid Rebate Program and rebate agreement with HCFA, Bayer generally agreed: (i) to report quarterly to HCFA its average manufacturer price and Best Price for its drug products, as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(1)(C); and (ii) to pay quarterly rebates to the states based on the product of (a) the units of each dosage form and strength paid for under the State Medicaid plan during the rebate period as reported by the state, and (b) the greater of the difference between the average manufacturer price and Best Price, or a minimum rebate percentage of the average manufacturer price, as further defined in 42 U.S.C. § 1396r-8(c)(1).

F. The state of Montana contends that it has certain civil claims against Bayer Corporation under the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, the Drug Pricing Program, 42 U.S.C. § 256b, other federal and state statutes, and/or common law doctrines for engaging in the following conduct:

(i) The state of Montana contends that, from Third Quarter 1995 through Third Quarter 2000, Bayer knowingly misreported its Best Price to HCFA and underpaid its Medicaid rebates for Cipro tablets by omitting the price of Cipro that was private labeled for Kaiser from its determination of Best Price;

(ii) The state of Montana contends that, from Second Quarter 1997 through Third Quarter 2000, Bayer knowingly misreported its Best Price to HCFA and underpaid its Medicaid rebates for Adalat CC by omitting the price of Adalat CC that was private labeled for Kaiser and PacifiCare from its determination of Best Price;

(iii) The state of Montana contends that, in May and June 1999, Bayer knowingly submitted false statements or records to the Office of Inspector General, Office of Audit Services, Department of Health and Human Services ("OIG-OAS") by (a) omitting material information about the price of Cipro tablets that was private labeled for Kaiser; (b) falsely stating that a higher priced package of Cipro was private labeled for Kaiser when it was not; and (c) falsely stating that the actual price at which Bayer sold Cipro to Kaiser was higher than Bayer's reported Best Price;

(iv) The state of Montana contends that, in First Quarter 1998, Bayer knowingly misreported its Best Price to HCFA and underpaid its Medicaid rebates for Adalat CC by omitting a \$100,000 payment made by Bayer to Prescription Solutions in connection with Adalat CC;

(v) The state of Montana contends that Bayer knowingly failed to list the Cipro that Bayer private labeled for Kaiser with the FDA to conceal the private labeling arrangement from the FDA and customers of Bayer's Cipro.

Bayer's conduct as described in the Criminal Action, the currently pending claims in the Civil Action, and this Preamble Paragraph are hereafter referred to as the "Covered Conduct."

G. The state of Montana represents that it does not have an administrative claim for exclusion against Bayer under the provisions for mandatory exclusion from the Medicare, Medicaid and other federal health care programs, 42 U.S.C. § 1320a-7(a) or corresponding state statutes, for Bayer's conviction in the Criminal Action or for the Covered Conduct, but alleges that it does have certain administrative claims for exclusion against Bayer under the provisions for permissive exclusion from the Medicare, Medicaid and other federal health care programs, 42 U.S.C. § 1320a-7(b) and corresponding state statutes, for the Covered Conduct.

H. Other than such admissions as Bayer makes in connection with its plea to the Information to which Bayer has agreed to enter a plea of guilty, which Bayer admits, Bayer denies the remaining allegations of the United States, relator(s) and the state of Montana as set forth herein. This Agreement does not constitute an admission by Bayer or evidence of any liability or wrongful conduct.

I. To avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final settlement as set forth below.

### III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. Bayer agrees to pay to the United States and to the Escrow Agent described below for distribution to the states and the District of Columbia that execute a state settlement agreement that has also been executed by Bayer ("Participating States") the sum of two-hundred, forty-two million, one-hundred twenty-six thousand, five-hundred eighty dollars (\$242,126,580)



(the "Medicaid Settlement Amount") and any pre-transfer interest as set forth in Section III.1.A and III.1.B herein. Payments to the United States and to the Participating States shall be made pursuant to the following terms and conditions:

A. Bayer has agreed to pay to the United States the sum of one-hundred, thirty-three million, one-hundred and sixty-nine thousand, six-hundred and nineteen dollars (\$133,169,619) (the "Federal Medicaid Settlement Amount"), which represents the federal share of the Medicaid Settlement Amount and the share of the Medicaid Settlement Amount payable to the relator(s) in certain federal False Claims Act lawsuit(s). The Federal Medicaid Settlement Amount, plus any pre-transfer interest pursuant to Section III.1.A of the Federal Agreement, shall be paid pursuant to a civil settlement agreement entered between Bayer and the United States (the "Federal Agreement").

B. Bayer agrees to deposit into an escrow account the sum of one-hundred and eight million, nine-hundred, fifty-six thousand, nine-hundred and sixty-one dollars (\$108,956,961) (the "State Medicaid Settlement Amount"), which represents the state-funded portions of the claims settled for the Medicaid programs of all states (except Arizona) and the District of Columbia. Bayer shall pay the State Medicaid Settlement Amount, plus any pre-transfer interest pursuant to Section III.1.B of the Federal Agreement, into the escrow account no later than seven business days after Bayer receives written transfer instructions from the negotiating team for the National Association of Medicaid Fraud Control Units ("NAMFCU Negotiating Team") and following the latest of the dates on which the following occurs: (1) the Federal Agreement is fully executed by the Parties and delivered to Bayer's attorneys, (2) the Escrow Agreement is executed by or on behalf of the Participating States and Bayer, and (3) the Court accepts the Fed. R. Crim. P. 11(e)(1)(C) guilty plea in connection with the Criminal Action as described in Preamble Paragraph II.B, and imposes the agreed upon sentence. The escrow account into which Bayer shall deposit the State Medicaid Settlement Amount shall be an account under the custody and control of the Medicaid Fraud Control Unit of the state of New